K081357

SEP - 5 2008

Eizo GmbH, Siemensallee 84, 76187 Karlsruhe

Food and Drug Administration
Center for Devices and Radiological Health (HFZ-401)
9200 Corporate Blvd.
Rockville, MD, USA
20850

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Date 6 May 2008

510(k) Summary (in accordance with 21 CFR 807.92)

1. **Date of Summary**
   6 May, 2008

2. **Company**
   EIZO GmbH
   Siemensallee 84
   D-76187 Karlsruhe, Germany

3. **Authorized Contact Person**
   James Berge

4. **Device Information**
   - Trade Name/Model: 6GF6201-5C$2# (where $ = A-Z and # = 0-9)
   - Common Name: Display, 5MP Grayscale Flat Panel Display
   - Classification Name: System, Image Processing
   - Classification Number: 21 CFR 892.2050, Product Code LLZ

5. **Predicate Devices**
   - Coronis 5MP (K042221)
   - Nio 5MP-M-21" (K062131)

6. **Device Description**
   The 6GF6201-5C$2# is a diagnostic 5MP grayscale flat panel display for viewing medical images. With the calibrated gamma response stored in five internal lookup tables, the display is suitable for use with a wide range of DVI graphic controller boards. The display can be used in single-head or multi-head configurations.

7. **Intended Use**
   The 5MP Grayscale Flat Panel Display is intended to be used in displaying and viewing digital images, including digital mammography, for review, analysis and diagnosis by trained medical practitioners. Patients do not come into contact with the display and the display does not control any life-sustaining devices.

8. Technological Characteristics

The 5MP Grayscale Flat Panel Display uses a monochrome LCD panel employing in-plane switching (IPS) technology to allow wide viewing angles. It has a resolution of 2048x2560 pixels and can be used in portrait and landscape modes. The display uses an integrated luminance sensor (ISS) to automatically stabilize the set luminance levels of the CCFL backlight over time. It also sports a front luminance sensor (ICS) for independent grayscale verification. The factory calibrated gamma response is stored in five lookup tables located in the display, allowing users to adapt the display to local lighting conditions and ensuring that the display function is DICOM compliant regardless of the display controller used.

The 5MP Grayscale Flat Panel Display will be offered both with and without an optional protective glass screen and may be offered in different housing colors. These cosmetic differences are reflected in the designators represented by the characters "$" and "#" included in the model trade name 6GF6201-5C$2#, where $ represents a letter between A and Z, and # is a number between 0 and 9.

The 5MP Grayscale Flat Panel Display uses the same LCD panel as the predicate devices and employs CCFL backlight technology. It is equipped with two integrated luminance sensors, one mounted rear center, as designed in the Nio 5MP-M-21", and a built in front sensor, as included with the Coronis 5MP.

The housing, stand, electronics and the integrated luminance sensors are not the same as those components used in the predicate devices. The overall design of the 6GF6201-5C$2# was validated in accordance with internationally recognized safety and EMC standards by independent testing facilities. Additionally, EIZO GmbH performed a range of system and performance tests to ensure that the 5MP Grayscale Flat Panel Display performed in accordance with its specifications. None of the tests revealed behaviors inconsistent with the expected performance of a 5MP grayscale flat panel display.

While the predicate devices are specified to operate with proprietary display controllers such as the BarcoMed Nio or BarcoMed Coronis boards, the 6GF6201-5C$2# was designed to receive and display images from standard, commercial DVI display controllers.

The 6GF6201-5C$2# can be used in conjunction with the SMfit Total Care software package to select an internal lookup table, display test patterns, calibrate the display and view additional information about the display and peripheral devices such as external photometers.

9. Conclusion

The 5MP Grayscale Flat Panel Display is substantially equivalent to the predicate devices with respect to technical characteristics, application and intended use. Major components are the same, and those that are different have been validated, both the independent testing and internal performance tests. Any differences between the devices do not affect safety or effectiveness.

The 510(k) Pre-Market Notification for the 6GF6201-5C$2# contains sufficient information and data to enable FDA - CDRH to determine substantial equivalence to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. James Berge
Product Manager
EIZO GmbH
Siemensallee 84, Karlsruhe, 76187
GERMANY

Re: K081357
Trade/Device Name: 5MP Grayscale Flat Panel Display, Model: 6GF6201-5C$2#
(Where $ = A-Z and # = 0-9)
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: July 29, 2008
Received: August 6, 2008

Dear Mr. Berge:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K081357

Device Name: 5MP Grayscale Flat Panel Display
Model: 6GF6201-5C$2# (where $ = A-Z and # = 0-9)

Indications For Use: The 5MP Grayscale Flat Panel Display is intended to be used in displaying and viewing digital images, including digital mammography, for review, analysis and diagnosis by trained medical practitioners.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K081357